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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,944	02/26/2004	William R. Patterson	355492-3100	5793

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,944	PATTERSON ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *1-6,17-19,21-35 and 48-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-16,20 and 36-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/15/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 02/21/2007 is acknowledged. The traversal is on the ground(s) that a search for the entire application on its merits can be conducted without a serious burden on the examiner. This is not found persuasive because In the instant case the process as claimed can be used to make another and materially different product such as an embolic composition which does not possess a hydroxyl-containing rheological modifier. In addition, the product as claimed can be sterilized by another and materially different process such as heat sterilization or chemical sterilization. Thus a search for one of the inventions of Groups I or II would not necessarily result in a search for the other invention, thus it would be a burden for the examiner to search for the entire application on its merits.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election without traverse of the species A in the reply filed on 02/21/2007 is acknowledged. Applicants stated in their response to the election restriction that claims 7-16,20,36-50 read on the elected claims. The examiner disagrees since claims 48-50 pertain to non-elected species B as defined in the previous office action dated 12/29/2006, therefore claims 48-50 were withdrawn by the examiner. The examiner has withdrawn claims 1-6,17-19,21-35 and 48-50 for pertaining to non-elected material.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-16 and 36-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically applicants claim a hydroxyl containing rheological modifier in an effective amount to impart shear thinning while the specification only gives written support for a limited number of types of rheological agents that can be used in the invention. Specific examples of the types of rheological modifiers include fumed silica, poly(2-hydroxyethyl-acrylates), copolymers of ethylene and maleic acid, polyvinylalcohol, hydroxypropylcellulose, hydroxypropyl-methylcellulose, carboxymethylcellulose, sodium hydroxyethylcellulose, hydroxylethyl-cellulose, methylcellulose and poly(2-hydroxy-ethylmethacrylates).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-16 and 36-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically claims 7 and 36 recite "a hydroxyl-containing rhelogical in an effective amount to impart sheer thinning", it is not clear from this recitation exactly what an effective amount would comprise. The term " effective

amount " in claims 7 and 36 is a relative term, which renders the claim indefinite. The term " effective amount " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is suggested by the examiner that applicants delete the term "effective amount" is deleted and replaced with a concentration or weight percent of the rheological modifier supported within the specification. To expedite the examining process the examiner simply searched for an effective amount of the rheological modifier to have a disclosed effect on the composition.

Also the term "minimal change" in claims 7 and 36 is a relative term which renders the claim indefinite. The term "minimal change" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is suggested by the examiner that the term "minimal change" is deleted from the claims.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 7-16,20 and 36-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Kaleta et al. (US 5,618,522).

Kaleta teaches oil in water emulsions compositions comprising a particulate thickener particularly fumed silica sold under the trade name CAB-O-Sil TS-720, described in applicants specifications [0251] as a commercially available silica which has been surface treated to provide for essentially no surface silanol groups. See col 2 lin 55-col 3 lin 18, col 6 lin 33-67, col 8 lin 41-62. Regarding the limitations that the composition is an embolic composition the examiner did not give the intended use of the preamble any patentable weight, ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); Kropa v. Robie, 187 F.2d at 152, 88 USPQ2d at 480-81. See col 12 lin 35-col 18 lin 34. Regarding claims 14 and 45 Kaleta discloses that additional thickening agents can be employed which include polysaccharides, carboxylic acid polymers, polyacrylamide polymers ect., thus meeting the limitation of a biocompatible polymer; also several biocompatible solvents were recited. Regarding claims 10-13 and 41-44 since the claimed composition is not patentably distinct from the Kaleta patent and the compositions as currently claimed are the same they will have the same shelf life characteristics such as viscosity change. Regarding claims 15-16 and 46-47, since the claimed composition is not patentably distinct from the Kaleta patent and the compositions as currently claimed are the same they will have the same viscosity of a composition in the absence of the rheological agent.

Claims 7-16,20 and 36-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Unger et al. (US 6,139,819).

Unger teaches compositions that comprise a lipid, protein, polymer (including numerous biocompatible polymers) and/or surfactant, and a gas in combination with a contrast agent. See abstract, col 22 lin 25-37, col 30 lin 59-col 31 lin 45. Regarding the limitation that the embolic composition is sterilized, it is inherent that since the compositions of Unger are administrable by injection they would be sterile. See col 11 lin 4-12. The compositions are disclosed as useful in targeting and treating arrhythmic disorders particularly atrial fibrillation, which may increase the risk for formation of coagula, particularly emboli and thrombi. See col 15 lin 62-col 16 lin 16. The composition can further comprise viscosity modifiers including silicon dioxide and methylcellulose. See col 33 lin 44-col 34 lin 16. Methylcellulose is considered by the examiner to meet the limitation of a rheological modifier in which the hydroxy groups have been converted to non-hydroxl groups, methylcellulose is a modified cellulose in which the hydroxyl groups of cellulose have been converted to the methyl ester. The remarks above in the Kaleta patent for the preamble intended use, the shelf life claims 10-13 and 41-44 and the viscosity of a composition in the absence of a rheological agent claims 15-16 and 46-47 are incorporated herein as well.

Claims 7-13 and 36-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Greff et al. (US 5,580,568).

Greff teaches compositions for use in embolizing blood vessels, the compositions comprise cellulose diacetate a biocompatible solvent and a water insoluble contrasting agent. See abstract, col 2 lin 37-col 4 lin 67. While Greff is drawn to cellulose diacetate compositions, the patent does teach that cellulose triacetate celluloses were already

well known in the art at the time of the invention to be useful in embolic compositions. Regarding the limitation that the embolic composition is sterilized, it is inherent that since the compositions of Greff are administrable by injection they would be sterile. The remarks above in the Kaleta patent for the preamble intended use, the minimal change in thixotropic behavior product by process limitation, the shelf life claims 10-13 and 41-44 and the viscosity of a composition in the absence of a rheological agent claims 15-16 and 46-47 are incorporated herein as well.

Claims 7-16,20 and 36-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Porter et al. (WO 2004/035022 A1, disclosed by applicants).

Porter teaches compositions comprising biocompatible solvents, polymers, contrast agents, biocompatible solvents and rheological modifiers including fused silica and methylcellulose. See abstract, [0006],[0014]-[0016],[0032]-[0046]. The amount of rheological modifier was sufficient to permit the composition to exhibit thixotropic behavior, permitting the compositions to exhibit high viscosities under static conditions while maintaining excellent flow properties under stress. See [0003]. The compositions were stated as being useful in embolizing a blood vessel. See [0021]. Regarding the limitation that the embolic composition is sterilized, it is inherent that since the compositions of Porter are administrable by catheter into the body they would be sterile. The remarks above in the Kaleta patent for the preamble intended use, the minimal change in thixotropic behavior product by process limitation, the shelf life claims 10-13 and 41-44 and the viscosity of a composition in the absence of a rheological agent claims 15-16 and 46-47 are incorporated herein as well.

Claims 7-16 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Porter et al. (US 2003/0039696 A1).

Porter teaches liquid polymer embolic compositions comprising rheology modifying agents including fumed silica. See abstract, [0001], [0017],[0041] and [0046]-[0048]. The rheology modifying agent was said to demonstrate thixotropic, pseudo-plastic, or plastic fluid behavior. Regarding the limitation that the embolic composition is sterilized, it is inherent that since the compositions of Porter are administrable by catheter into the body they would be sterile. [0019]

Claims 7-16 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Greff (US 2003/0228273 A1)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Greff teaches embolizing compositions comprising a biocompatible polymer, contrast agent, thickening agent (including fumed silica) and a biocompatible solvent. See abstract and [0037]. Regarding the limitation that the embolic composition is sterilized, it is inherent that since the compositions of Greff are administrable by catheter into the body they would be sterile. [0044]

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-13 and 36-39,41-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 5,580,568. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim embolizing compositions comprised of a hydroxyl containing rheological agent, wherein some of the hydroxyl groups have been converted to non-hydroxy groups.

Claims 7-16,20 and 36-39,41-44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 24 of copending Application No. 10/789,436. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim embolizing compositions comprised of a hydroxyl containing rheological agent furmed

silica or wherein some of the hydroxyl groups have been converted to non-hydroxy groups.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER